Approval Date: February 24, 1994

FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number

ANADA 200-088

B. Sponsor

Fort Dodge Laboratories
P.O. Box 518
Fort Dodge, Iowa 50501

C. Proprietary Name

Sedazine™

D. Established Name

xylazine hydrochloride

E. Dosage Form

Solution

F. Dosage Regimen

Intravenous: 0.5 mL/100 lbs body weight (0.5 mg/lb)
Intramuscular: 1.0 mL/100 lbs body weight (1.0 mg/lb)

Cervidae
Fallow Deer (Dama dama): 2.0 to 4.0 mL/100 lbs body weight (2.0 to 4.0 mg/lb).
Mule Deer (Odocoileus hemionus), Sika Deer (Cervus nippon) and White-Tailed Deer (Odocoileus virginianus): 1.0 to 2.0 mL/100 lbs body weight (1.0 to 2.0 mg/lb)

Elk (Cervus canadensis): 0.25 to 0.5 mL/100 lbs body weight (0.25 to 0.5 mg/lb)

G. Route of Administration

Intramuscular (Cervidae)

H. Indication

Sedazine (xylazine) should be used in horses and Cervidaewhen it is desirable to produce a state of sedation accompanied by a shorter period of analgesia.

Horses: Sedazine has been used successfully as follows:

1. Diagnostic procedures -- oral and opthalmic examinations, abdominal palpation, rectal palpation, vaginal examination, catheterization of the bladder and radiographic examinations.
2. Orthopedic procedures, such as application of casting materials and splints.
3. Dental procedures.

4. Minor surgical procedures of short duration such as debridement, removal of cutaneous neoplasms and suturing of lacerations.
5. To calm and facilitate handling of fractious animals.
6. Therapeutic medication for sedation and relief of pain following injury or surgery.
7. Major surgical procedures:
    a. When used as a preanesthetic to general anesthesia.
    b. When used in conjunction with local anesthetics.

Cervidae: Sedazine may be used for the following:
To calm and facilitate the handling of fractious animals.

1. Diagnostic procedures.
2. Minor surgical procedures.
3. Therapeutic medication for sedation and relief of pain following injury or surgery.
4. As a preanesthetic to local anesthesia. Sedazine at the recommended dosages can be used in conjunction with local anesthetics, such as procain or lidocaine.

II. EFFECTIVENESS AND TARGET ANIMAL SAFETY

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act, (53 FR 50460, December 15, 1988; First GADPTRA Policy Letter), an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). For certain dosage forms, the Agency grants a waiver from conducting an in vivo bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter). In lieu of bioequivalence testing, the safety and efficacy of the generic product are based on the demonstrated chemical equivalence to the pioneer product.

Based upon the information provided for the generic product, Fort Dodge Laboratories was granted a waiver December 13, 1989 (see section 4) from conducting an in vivo bioequivalence study with xylazine hydrochloride. The generic product is a solution containing the same active and inactive ingredients as the pioneer product. It is intended solely for intravenous and intramuscular injection.

III. HUMAN FOOD SAFETY

Human Safety Relative to Food Consumption:
Regarding consumption of drug residues in food, human safety data were not required for approval of this ANADA. This drug is labeled for use in horses and Cervidaenot intended for food.

Human Safety Relative to Possession, Handling, and Administration:
Labeling contains adequate caution/warning statements.

WAIVER LETTER

GC-1814

John R. Eppley, B.S., D.V.M. Associate Director, Quality Assurance & Regulatory Affairs
Fort Dodge, Iowa 50501

Dear Dr. Eppley:

We refer to your letter dated October 17, 1989, regarding a generic copy of Rompun (Xylazine) Injectable for intravenous and intramuscular injection in horses.

You requested a waiver from in vivo bioequivalence testing and submitted information on the components and composition of your proposed product.

Based on the information you provided, your proposed product is a solution containing the same active and inactive ingredients as the pioneer product. It is intended solely for intravenous and intramuscular injection. It is, therefore, eligible for waiver from in vivo bioequivalence testing under our current policy.

Your Request for Waiver is granted. It is granted, however, on the condition that the full information presented in your Abbreviated New Animal Drug Application continues to show that your proposed generic product is chemically equivalent to the pioneer product. If it is not, in vivo bioequivalence testing could be required.

In submitting your ANADA, please refer to the number at the top of this letter and include a copy of this correspondence in your original submission.

Sincerely,

Thomas J. McKay, Ph.D
Generic Animal Drug Staff
Center for Veterinary Medicine

IV. AGENCY CONCLUSIONS

This ANADA satisfies the requirements of section 512 of the Act and demonstrates that xylazine hydrochloride is safe and effective for its labeled indications when used under its proposed conditions of use.

The format of this FOI Summary document has been modified from its original form to conform with Section 508 of the Rehabilitation Act (29 U.S.C. 794d). The content of this document has not changed.